DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 7 2006

Re: Macugen
Docket No.: 05E-0234

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,051,698, filed by Gilead Sciences, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Macugen, the human drug product claimed by the patent.

The total length of the regulatory review period for Macugen is 2,312 days. Of this time, 2,128 days occurred during the testing phase and 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 21, 1998.

   The applicant claims August 20, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 21, 1998, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: June 17, 2004.

   The applicant claims March 17, 2004, as the date the new drug application (NDA) for Macugen (NDA 21-756) was initially submitted. The applicant claims this is the date it submitted the first unit of NDA 21-756, which was submitted in several units as part of a rolling NDA submission procedure. It is FDA's position that the approval phase begins when the marketing application is complete. A review of FDA records reveals that the final module of the marketing application was submitted on June 17, 2004, which is considered to be the NDA initially submitted date.

3. The date the application was approved: December 17, 2004.

FDA has verified the applicant's claim that NDA 21-756 was approved on December 17, 2004.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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